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## PENT COOPERATION TREATY

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ELI LILLY AND COMPANY

Patent Division

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From the  
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:  
 DANICA HOSTETTLER  
 ELI LILLY AND COMPANY  
 P. O. BOX 6288  
 INDIANAPOLIS, IN 46206-6288

NOTIFICATION OF TRANSMITTAL OF  
INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT

(PCT Rule 71.1)

Date of Mailing  
(day/month/year)

04 JUN 2004

Applicant's or agent's file reference

## IMPORTANT NOTIFICATION

X-15199✓

International application No.  
200  
PCT/US03/05046 ✓International filing date (day/month/year)  
27 February 2003 (27.02.2003)Priority date (day/month/year)  
08 March 2002 (08.03.2002)

Applicant

ELI LILLY AND COMPANY

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. REMINDER

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices)(Article 39(1))(see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

Name and mailing address of the IPEA/US  
 Mail Stop PCT, Attn: IPEA/US  
 Commissioner for Patents  
 P.O. Box 1450  
 Alexandria, Virginia 22313-1450  
 Facsimile No. (703) 305-3230

Authorized officer  
 Jon P. Weber, Ph.D.  
 Telephone No. 571-272-0700

Form PCT/IPEA/416 (July 1992)

## INTERNATIONAL COOPERATION TREATY

## PCT

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

|   |  |   |
|---|--|---|
| Applicant's or agent's file reference<br><b>X-15199</b>   | FOR FURTHER ACTION   | See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416) |
| International application No.<br><b>PCT/US03/05046</b>  | International filing date (day/month/year)<br><b>27 February 2003 (27.02.2003)</b> | Priority date (day/month/year)<br><b>08 March 2002 (08.03.2002)</b>                                 |
| International Patent Classification (IPC) or national classification and IPC<br><b>IPC(7): A61K 38/48; C12N 9/48, 9/96 and US Cl.: 424/94.64 ; 435/212, 188</b> |  |   |
| Applicant<br><b>ELI LILLY AND COMPANY</b>   |  |   |

|  |
|--|
| <ol style="list-style-type: none"> <li>This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</li> <li>This REPORT consists of a total of <u>3</u> sheets, including this cover sheet.</li> </ol> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of <u>—</u> sheets.</p>  |
| <ol style="list-style-type: none"> <li>This report contains indications relating to the following items:           <ul style="list-style-type: none"> <li>I <input checked="" type="checkbox"/> Basis of the report</li> <li>II <input type="checkbox"/> Priority</li> <li>III <input type="checkbox"/> Non-establishment of report with regard to novelty, inventive step and industrial applicability</li> <li>IV <input type="checkbox"/> Lack of unity of invention</li> <li>V <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li> <li>VI <input type="checkbox"/> Certain documents cited</li> <li>VII <input type="checkbox"/> Certain defects in the international application</li> <li>VIII <input type="checkbox"/> Certain observations on the international application</li> </ul> </li> </ol> |

|  |   |
|--|---|
| Date of submission of the demand<br><b>25 September 2003 (25.09.2003)</b>  | Date of completion of this report<br><b>04 March 2004 (04.03.2004)</b>  |
| Name and mailing address of the IPEA/US<br><b>Mail Stop PCT, Attn: IPEA/US<br/>Commissioner for Patents<br/>P.O. Box 1450<br/>Alexandria, Virginia 22313-1450<br/>Facsimile No. (703) 305-3230</b> | Authorized office<br><br><b>Jon P. Weber, Ph.D.</b><br>Telephone No. 571-272-0700 |

Form PCT/IPEA/409 (cover sheet)(July 1998)

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## I. Basis of the report

## 1. With regard to the elements of the international application:\*

 the international application as originally filed. the description:

pages 1-19 as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_. the claims:

pages 20-22, as originally filed

pages NONE, as amended (together with any statement) under Article 19pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_. the drawings.pages NONE, as originally filedpages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_. the sequence listing part of the description:

pages 1-6, as originally filed

pages NONE, filed with the demandpages NONE, filed with the letter of \_\_\_\_\_.

## 2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

 the language of a translation furnished for the purposes of international search (under Rule 23.1(b)). the language of publication of the international application (under Rule 48.3(b)). the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

## 3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

 contained in the international application in printed form. filed together with the international application in computer readable form. furnished subsequently to this Authority in written form. furnished subsequently to this Authority in computer readable form. The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished. The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished4.  The amendments have resulted in the cancellation of: the description, pages NONE the claims, Nos. NONE the drawings, sheets/figs NONE5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application no.  
PCT/US03/05046**V. Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement****1. STATEMENT**

|                               |             |     |
|-------------------------------|-------------|-----|
| Novelty (N)                   | Claims 1-25 | YES |
|                               | Claims NONE | NO  |
| Inventive Step (IS)           | Claims 1-25 | YES |
|                               | Claims NONE | NO  |
| Industrial Applicability (IA) | Claims 1-25 | YES |
|                               | Claims NONE | NO  |

**2. CITATIONS AND EXPLANATIONS**

Claims 1-25 meet the criteria for novelty, inventive step and industrial applicability set out in PCT Article 33(2)-(3), because the prior art does not teach or fairly suggest a pharmaceutical composition comprising activated protein C and a chelating agent. This product is expected to be useful in various methods that require the use of activated protein C.